

## OraSure QuickFlu® Annual Reactivity Testing Results

The following tables summarize the results of annual reactivity testing performed using 2017 CDC influenza viruses panel (Lot No. 170428, exp. date 01/May/2018) as required by 21 CFR 866.3328(b).

Table A: CDC human influenza virus A panel test results

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID <sub>50</sub> /mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)									
		10 <sup>9.3</sup>	8x 10 <sup>6.3</sup>	1.6x 10 <sup>6.3</sup>	3.2x 10 <sup>5.3</sup>	6.4x 10 <sup>4.3</sup>	1.28x10 <sup>4.3</sup>	2.56x10 <sup>3.3</sup>	5.12x10 <sup>2.3</sup>		
A(H1N1)	A/Brisbane/59/2007	10 <sup>9.3</sup>	8x 10 <sup>6.3</sup>	1.6x 10 <sup>6.3</sup>	3.2x 10 <sup>5.3</sup>	6.4x 10 <sup>4.3</sup>	1.28x10 <sup>4.3</sup>	2.56x10 <sup>3.3</sup>	5.12x10 <sup>2.3</sup>		
		n/a	5/5	5/5	5/5	5/5	5/5	0/5	0/5		
A(H1N1)	A/Fujian Gulow/1896/2009	10 <sup>9.2</sup>	8x 10 <sup>6.2</sup>	1.6x 10 <sup>6.2</sup>	3.2x 10 <sup>5.2</sup>	6.4x 10 <sup>4.2</sup>	1.28x10 <sup>4.2</sup>	2.56x10 <sup>3.2</sup>	5.12x10 <sup>2.2</sup>	1.02x10 <sup>2.2</sup>	2.05x10 <sup>1.2</sup>
		n/a	5/5	5/5	5/5	5/5	5/5	5/5	4/5	0/5	0/5
A(H3N2)	A/Perth/16/2009	10 <sup>8.9</sup>	8x 10 <sup>5.9</sup>	1.6x 10 <sup>5.9</sup>	3.2x 10 <sup>4.9</sup>	6.4x 10 <sup>3.9</sup>					
		n/a	5/5	5/5	0/5	0/5					
A(H3N2)	A/Hong Kong/4801/2014	10 <sup>7.9</sup>	8x 10 <sup>4.9</sup>	1.6x 10 <sup>4.9</sup>	3.2x 10 <sup>3.9</sup>	6.4x 10 <sup>2.9</sup>	1.28x10 <sup>2.9</sup>	2.56x10 <sup>1.9</sup>	5.12x10 <sup>0.9</sup>	1.02x10 <sup>0.9</sup>	2.05x10 <sup>-0.1</sup>
		n/a	5/5	5/5	5/5	5/5	5/5	5/5	5/5	0/5	0/5
A(H1N1)pdm09	A/California/07/2009	10 <sup>9.5</sup>	8x 10 <sup>6.5</sup>	1.6x 10 <sup>6.5</sup>	3.2x 10 <sup>5.5</sup>	6.4x 10 <sup>4.5</sup>	1.28x10 <sup>4.5</sup>				
		n/a	5/5	5/5	5/5	0/5	0/5				
A(H1N1)pdm09	A/Michigan/45/2015	10 <sup>8.3</sup>	8x 10 <sup>5.3</sup>	1.6x 10 <sup>5.3</sup>	3.2x 10 <sup>4.3</sup>	6.4x 10 <sup>3.3</sup>					
		n/a	5/5	4/5	0/5	0/5					

Table B: CDC human influenza virus B panel test results

Influenza Virus (Type/Subtype)	Virus Strain Name	Virus Serial Dilution Concentration (EID <sub>50</sub> /mL) and Number of Positive Results at Each Dilution (no. of positives /5 replicates)									
		10 <sup>9.9</sup>	4x 10 <sup>7.9</sup>	8x 10 <sup>6.9</sup>	1.6x 10 <sup>6.9</sup>	3.2x 10 <sup>5.9</sup>	6.4x 10 <sup>4.9</sup>	1.28x 10 <sup>4.9</sup>	2.56x10 <sup>3.9</sup>		
(Victoria lineage)	B/Brisbane/60/2008	10 <sup>9.9</sup>	4x 10 <sup>7.9</sup>	8x 10 <sup>6.9</sup>	1.6x 10 <sup>6.9</sup>	3.2x 10 <sup>5.9</sup>	6.4x 10 <sup>4.9</sup>	1.28x 10 <sup>4.9</sup>	2.56x10 <sup>3.9</sup>		
		n/a	5/5	5/5	5/5	5/5	4/5	0/5	0/5		
(Victoria lineage)	B/Texas/02/2013	10 <sup>9.1</sup>	4x 10 <sup>7.1</sup>	8x 10 <sup>6.1</sup>	1.6x 10 <sup>6.1</sup>	3.2x 10 <sup>5.1</sup>	6.4x 10 <sup>4.1</sup>	1.28x 10 <sup>4.1</sup>	2.56x10 <sup>3.1</sup>	5.12x10 <sup>2.1</sup>	1.02x10 <sup>2.1</sup>
		n/a	5/5	5/5	5/5	5/5	5/5	3/5	2/5	0/5	0/5
(Yamagata lineage)	B/Wisconsin/1/2010	10 <sup>6.9</sup>	4x 10 <sup>4.9</sup>	8x 10 <sup>3.9</sup>	1.6x 10 <sup>3.9</sup>	3.2x 10 <sup>2.9</sup>	6.4x 10 <sup>1.9</sup>	1.28x10 <sup>1.9</sup>	2.56x10 <sup>0.9</sup>		
		n/a	5/5	5/5	5/5	5/5	5/5	0/5	0/5		
(Yamagata lineage)	B/Phuket/3073/2013	10 <sup>9.9</sup>	4x 10 <sup>7.9</sup>	8x 10 <sup>6.9</sup>	1.6x 10 <sup>6.9</sup>	3.2x 10 <sup>5.9</sup>	6.4x 10 <sup>4.9</sup>	1.28x 10 <sup>4.9</sup>			
		n/a	5/5	5/5	5/5	2/5	0/5	0/5			